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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/856,571

05/23/2001

Thomas Himmler

M0-6341/LEA3

9929

7590

12/02/2004

Bayer Corporation  
400 Morgan Lane  
West Haven, CT

06516-4175

EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/856,571

Applicant(s)

HIMMLER ET AL.

Examiner

Binta M Robinson

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 4-24 is/are rejected.
- 7) ☒ Claim(s) 2,3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **Detailed Action**

A rejection of claims 1-5 and 12 over Bartel(Himmler) is withdrawn in light of applicant's comments filed 8/25/04. Claims 1-24 are pending in the application. The objection to claims 5-11 and 15-24 made in the office action mailed 2/25/04 is withdrawn because these claims are rejected below.

### ***New Claim Objections***

Applicant is advised that should claim 14 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Applicant is advised that should claim 9 be found allowable, claim 18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 4 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 2-3 are objected to because of the following informalities: Claim 2 is objected to because a period is not present at the end of the claim on page 5 but is present in line 4, page 4.

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Claim 3 is objected to because a period is present at line 4 as well as at the end of the claim. There should only be a period at the end of claim 3.

Appropriate correction is required.

Claim 5 objected to because of the following informalities: in line 8 of claim 5, page 8, the compound of (1S, 6S)-2, 8-diazabicyclo [4.3.0]nonane of the formula (III) is depicted with a "(II)" beside the structural formula. The "(II)" needs to be amended to a "(III)". Appropriate correction is required.

#### **New claim rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 4-8, 12, 13, 14, 15, are indefinite because it is unclear how the semihydrate of the CCDC is obtained when HCL is not mentioned as being used in the process. How can a semihydrochloride be formed if HCL is not used in the reaction and especially when the halogen in the reactant of compound II is not Cl but Flourine?

B. Claims 10, 18, 19, 20, 21 are unclear because they are method claims that are improperly dependent upon a compound claim 1. Claim 1 is not a process claim where CCDC is formulated in claim 1. In claim 1, CCDC is claimed as a compound and no process steps are discussed. Additionally, a pharmaceutical

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composition consists of at least two compounds rather than just one and can not be formed just by synthesizing CCDC, but must consist of a pharmaceutically acceptable carrier.

C. Claims 11, 22, 23, 24 are indefinite because the host being treated for bacterial infection is not stated.

D. In claims 9, 16-18, line 1, the term "customary" is indefinite. What auxiliaries and excipients are customary? Are these excipients and auxiliaries customary in the use of formulating any pharmaceutical composition or the pharmaceutical composition of the instant invention and are these excipients and auxiliaries – inert carriers?

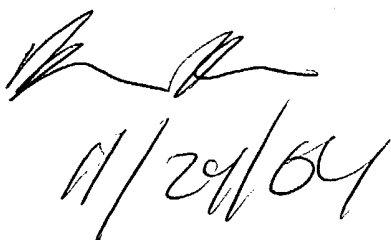
Claim 1 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

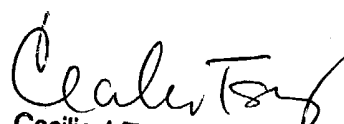
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.



Handwritten signature and date: 11/24/04



Cecilia J. Tsang  
Supervisory Patent Examiner  
Technology Center 1600